MAY 0 8 2014

Special 510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter Name, Address, Contact

Roche Diagnostics
9115 Hague Road, PO. Box 0416
Indianapolis, IN 46250-50416

Contact Person: Kelli Turner

- Phone: (317) 521-4515
- FAX: (317) 521-2324
- Email: kelli.turner@roche.com

Date Prepared: April 28, 2014

Device Name

Proprietary name:	Elecsys CK-MB STAT Immunoassay
Common name:	CK-MB STAT Assay
Classification name:	Colorimetric method; Cpk or Isoenzymes
Product Code:	JHY
Predicate Device:	CK-MB STAT Immunoassay, Roche Diagnostics (K132571)

Continued on next page

Special 510(k) Summary, *continued*

Establishment Registration

For the CK-MB STAT Assay, the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany, is 9610126 and for Penzberg, Germany, is 9610529. The establishment registration number for Roche Diagnostics United States is 1823260

Classification

- The FDA has classified the CK-MB STAT as a Class II device.

Panel	Product Code	Classification Name	Regulation Citation
Clinical Chemistry	JHY	Colorimetric Method, Cpk Or Isoenzymes	21 CFR 862.1215

Performance Standards

To date, no performance standards that affect this device have been finalized under Section 514 of the Act.

Proposed Labeling

Proposed draft labeling sufficient to describe the device, the intended use, and the directions for use on the **cobas e** 601 immunoassay analyzer is attached. We believe the draft version of the device labeling presented in Section V contains all of the technical information required per 21 CFR 809.10 for the CK-MB STAT (one-step incubation) Assays.

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Special 510(k) Summary, *continued*

Analyzer Platform

Precision of the CK-MB STAT (one-step incubation) assay was evaluated on one **cobas e** 601 Immunoassay Analyzers according to CLSI EP5-A2 guidelines. A method comparison between the Elecsys CK-MB STAT (two-step incubation) and CK-MB STAT (one-step incubation) was performed and summarized in Section III, 510(k) summary, Method Comparison.

Device Description

The CK-MB STAT (one-step incubation) Assay is a sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection.

Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration and a master curve (5-point-calibration) provided with the reagent bar code.

The CK-MB STAT (one-step incubation) application is identical to the CK-MB STAT (two-step incubation) assay, the only difference being for the CK-MB STAT (one-step incubation) application, the sample, reagent 1, reagent 2 and microparticles are added at one time.

Note: Calibrators and controls are packaged and sold separately.

Intended Use

Immunoassay for the *in vitro* quantitative determination of the MB isoenzyme of creatine kinase in human serum and plasma
The electrochemiluminescence immunoassay "ECLIA" is intended for use on the indicated and **cobas e** immunoassay analyzers.

Continued on next page

Special 510(k) Summary, *continued*

Indications for use	Immunoassay for the *in vitro* quantitative determination of the MB isoenzyme of creatine kinase in human serum and plasma. Measurements of the MB isoenzyme of creatinine kinase are used as an aid in the diagnosis of myocardial infarction. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the indicated Elecsys and **cobas e** immunoassay analyzers.
Special conditions for use	For prescription use only
Special instrument requirements	The electrochemiluminescence immunoassay "ECLIA" is intended for use on the indicated Elecsys and **cobas e** immunoassay analyzers.
Substantial Equivalence	The CK-MB STAT Immunoassay is substantially equivalent to other devices legally marketed in the United States. CK-MB STAT (one-step incubation) Immunoassays, is equivalent to CK-MB STAT (two-step) Immunoassay, Roche Diagnostics (K132571).
Substantial Equivalence Comparison	The following table compares the CK-MB STAT Immunoassay (one-step incubation) with the predicate device.

Continued on next page

Special 510(k) Summary, *continued*

Comparison of Assays, Similarities and Differences

Table 1 CK-MB STAT (two-step incubation) vs. CK-MB STAT (one-step incubation)

Assay Comparison		
Feature	**Predicate Device: Elecsys CK-MB STAT (two-step incubation) Assay (K132571)**	**CK-MB STAT (one-step incubation) Assay (modified)**
General Assay Features		
Intended Use/ Indications for Use	Immunoassay for the *in vitro* quantitative determination of MB isoenzyme of creatine kinase in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.	Same
Assay Protocol	Two step Sandwich assay using biotinylated and ruthenium labeled antibodies and streptavidin microparticles	Sandwich assay using biotinylated and ruthenium labeled antibodies and streptavidin microparticles
Detection Protocol	Electrochemiluminescent Immunoassay	Same
Applications	STAT (9 minute) application	Same

Continued on next page

Special 510(k) Summary, *continued*

Comparison of Assays—Similarities and Differences, *continued*

Table 1 ***continued***

<table>
<tr><th colspan="3">Assay Comparison</th></tr>
<tr><th>Feature</th><th>Predicate Device: Elecsys CK-MB STAT (two-step incubation) Assay (K132571)</th><th>CK-MB STAT (one-step incubation) Assay (modified)</th></tr>
<tr><td colspan="3">General Assay Features</td></tr>
<tr><td>Instrument Platform</td><td>cobas e 411</td><td>Roche cobas e 601</td></tr>
<tr><td>Sample Volume</td><td>15 µL</td><td>Same</td></tr>
<tr><td>Sample Type</td><td>Human serum and plasma treated with K_2-EDTA, K_3-EDTA, and lithium heparin and sodium heparin plasma.
<table>
<tr><th></th><th>Specification</th><th>Na Heparin Plasma</th><th>Li Heparin Plasma</th><th>K_2-EDTA Plasma</th><th>K_3-EDTA Plasma</th></tr>
<tr><td>Sample size normally filled tubes</td><td>at least 30</td><td>35</td><td>34</td><td>35</td><td>35</td></tr>
<tr><td>Slope (BaPa)</td><td>0.9 - 1.1</td><td>0.994</td><td>0.996</td><td>1.020</td><td>0.988</td></tr>
<tr><td>Intercept (BaPa)</td><td>≤ +/- 0.15</td><td>-0.0010</td><td>0.0045</td><td>-0.0082</td><td>-0.0115</td></tr>
<tr><td>Correlation r</td><td>> 0.95</td><td>0.9997</td><td>0.9996</td><td>0.9999</td><td>0.9998</td></tr>
<tr><td>Relative deviation for single sample pairs</td><td>+/- 20%</td><td>max deviation 14.6 %</td><td>max deviation 12.0 %</td><td>max deviation 10.5 %</td><td>max deviation 8.7 %</td></tr>
</table></td><td>Same</td></tr>
<tr><td>Reagents</td><td>Sandwich principle. Total duration of assay: 9 minutes.
• 1st incubation: 15 µL of sample, a biotinylated monoclonal anti-CK-MB antibody, and a monoclonal CK-MB-specific antibody labeled with a ruthenium complex react to form a sandwich complex.
• 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.</td><td>Sandwich principle. Total duration of assay: 9 minutes
• Antigen in the sample (15 µL), a biotinylated monoclonal anti-CK-MB antibody, a monoclonal CK-MB-specific antibody labeled with a ruthenium complex and streptavidin-coated microparticles react to form a sandwich complex, which is bound to a solid phase</td></tr>
</table>

Continued on next page

Special 510(k) Summary, *continued*

Comparison of Assays—Similarities and Differences, *continued*

Table 1 ***continued***

Assay Comparison		
Feature	**Predicate Device: Elecsys CK-MB STAT (two-step incubation) Assay (K132571)**	**CK-MB STAT (one-step incubation) Assay (modified)**
General Assay Features		
Calibrator	CK-MB STAT CalSet	Same
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: • After 12 weeks when using the same reagent lot. • After 7 days (when using the same reagent kit on the analyzer). • As required: e.g. quality control findings outside the specified limits	Same
Controls	Elecsys PreciControl Cardiac II	Same

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Special 510(k) Summary, *continued*

Comparison of Assays—Similarities and Differences, *continued*

Table 1 ***continued***

Assay Comparison		
Feature	**Predicate Device: Elecsys CK-MB STAT (two-step incubation) Assay (K132571)**	**CK-MB STAT (one-step incubation) Assay (modified)**
General assay features		
Traceability / Standardization	The CK-MB STAT assay is traceable to the Abbott IMx CK-MB assay and linearized using human recombinant CK-MB from Seradyn	Same
Reagent Stability	Unopened: 2-8°C - Up to the stated expiration date Opened 2-8°C - 12 weeks On Analyzers – 8 weeks	Same
Linearity determined with serum samples.	Series 1: y=0.9421 -0.0579 Series 2: y=0.9348-0.116 Series 3: y=0.942-0.0964	Series 1: y=0.9571 -0.1267 (range: 0.27 to 563 ng/mL) Series 2: y=0.9499-0.0957 (range: 0.13 to 548 ng/mL) Series 3: y=0.9576-0.1188 (range: 0.16 to 328 ng/mL) Note: linearity was established at ± 11.3% within the stated measuring range.

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Special 510(k) Summary, *continued*

Comparison of Assays—Similarities and Differences, continued

Table 1 *continued*

Assay Comparison		
Feature	**Predicate Device: Elecsys CK-MB STAT (two-step incubation) Assay (K132571)**	**CK-MB STAT (one-step incubation) Assay (modified)**
Labeled Performance Characteristics		
Measuring Range	1-300 ng/mL	Same
Precision	*cobas e 411:* Within-run (will be labeled Repeatability) 1.2% CV @ 5.46 ng/mL 1.3% CV @ 29.5 ng/mL 1.3% CV @ 93.5 ng/mL 1.5% CV @ 301 ng/mL 1.3% CV^{PC1} @ 4.44 ng/mL 1.4% CV^{PC2} @ 57.9 ng/mL Total (will be labeled Intermediate) 2.5% CV @ 5.46 ng/mL 4.2% CV @ 29.5 ng/mL 4.1% CV @ 93.5 ng/mL 3.3% CV @ 301 ng/mL 2.6% CV^{PC1} @ 4.44 ng/mL 3.0% CV^{PC2} @ 57.9 ng/mL	*cobas e 601:* Within-run (will be labeled Repeatability) 1.1% CV @ 5.34 ng/mL 1.1% CV @ 27.3 ng/mL 1.1% CV @ 89.2 ng/mL 0.8% CV @ 283 ng/mL 1.2% CV^{PC1} @ 4.27 ng/mL 0.9% CV^{PC2} @ 54.3 ng/mL Total (will be labeled Intermediate) 1.4% CV @ 5.34 ng/mL 3.2% CV @ 27.3 ng/mL 2.5% CV @ 89.2 ng/mL 2.2% CV @ 283 ng/mL 1.4% CV^{PC1} @ 4.27 ng/mL 1.3% CV^{PC2} @ 54.3 ng/mL
Analytical Sensitivity	Limit of Blank (LoB): = 0.1 ng/ml Limit of Detection (LoD): = 0.3 ng/ml Limit of Quantitation (LoQ): = 1 ng/ml Established according to CLSI EP17- A	Same

PC1=PreciControl Cardiac 1
PC2=PreciControl Cardiac 2

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Special 510(k) Summary, *continued*

Comparison of Assays—Similarities and Differences, *continued*

Table 1 ***continued***

<table>
<tr><th colspan="3">Assay Comparison</th></tr>
<tr><th>Feature</th><th>Predicate Device: Elecsys CK-MB STAT (two-step incubation) Assay (K132571)</th><th>CK-MB STAT (one-step incubation) Assay (modified)</th></tr>
<tr><th colspan="3">Labeled Performance Characteristics</th></tr>
<tr><td>Analytical Specificity</td><td><table><tr><th>Analyte</th><th>Reactivity</th></tr><tr><td>CK-MM</td><td>None</td></tr><tr><td>CK-BB</td><td>0.10%</td></tr></table></td><td>Same</td></tr>
<tr><td>Hook Effect</td><td>There is no high-dose hook effect at CK-MB concentrations up to 5000 ng/mL</td><td>Same</td></tr>
<tr><td>Limitations</td><td>Each interferent was evaluated at 11 numerical values. All samples were tested in duplicate. The results reported represent recovery of ± 10 % compared to the unspiked reference sample.

The results of the interferences are presented below:<table><tr><th>Interferent tested</th><th>No interference up to</th></tr><tr><td>Intralipid® (Lipemia)</td><td>2000 mg/dL</td></tr><tr><td>Biotin</td><td>50 ng/mL</td></tr><tr><td>Bilirubin</td><td>40 mg/dL</td></tr><tr><td>Hemoglobin</td><td>1000 mg/dL</td></tr><tr><td>Rheumatoid Factor</td><td>1700 IU/mL</td></tr><tr><td>Human Serum albumin</td><td>14 g/dL</td></tr><tr><td>Human IgG</td><td>7 g/dL</td></tr><tr><td>Human IgM</td><td>1 g/dL</td></tr><tr><td>Human IgA</td><td>1.6 g/dL</td></tr></table></td><td>Same</td></tr>
</table>

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Special 510(k) Summary, *continued*

<table>
<tr><th colspan="3">Assay Comparison</th></tr>
<tr><th>Feature</th><th>Predicate Device: Elecsys CK-MB STAT (two-step incubation) Assay (K132571)</th><th>CK-MB STAT (one-step incubation) Assay (modified)</th></tr>
<tr><th colspan="3">Labeled Performance Characteristics</th></tr>
<tr><td>Limitations, continued</td><td>In vitro tests were performed on 18 commonly used pharmaceuticals. No interference with the assay was found. Criterion: Recovery within ± 10% compared to the unspiked reference sample.

These included samples with the following:
<table>
<tr><th>Drug</th><th>Concentration</th></tr>
<tr><td>Acetylcysteine</td><td>150 mg/L</td></tr>
<tr><td>Ampicillin-Na</td><td>1000 mg/ L</td></tr>
<tr><td>Ascorbic acid</td><td>300 mg/ L</td></tr>
<tr><td>Ca- Dobesilate</td><td>200 mg/L</td></tr>
<tr><td>Cyclosporine</td><td>5 mg/L</td></tr>
<tr><td>Cefoxitin</td><td>2500 mg/L</td></tr>
<tr><td>Heparin</td><td>5000 U</td></tr>
<tr><td>Intralipid</td><td>10000 mg/L</td></tr>
<tr><td>Levodopa</td><td>20 mg/L</td></tr>
<tr><td>Methyldopa + 1.5 H_2O</td><td>20 mg/L</td></tr>
<tr><td>Metronidazole</td><td>200 mg/L</td></tr>
<tr><td>Phenylbutazone</td><td>400 mg/L</td></tr>
<tr><td>Doxycycline</td><td>50 mg/L</td></tr>
<tr><td>Acetylsalicylic Acid</td><td>1000 mg/L</td></tr>
<tr><td>Rifampicin</td><td>60 mg/L</td></tr>
<tr><td>Acetaminophen</td><td>200 mg/L</td></tr>
<tr><td>Ibuprofen</td><td>500 mg/L</td></tr>
<tr><td>Theophylline</td><td>100 mg/L</td></tr>
</table></td><td>Same</td></tr>
</table>

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Special 510(k) Summary, *continued*

<table>
<tr><th colspan="3">Assay Comparison</th></tr>
<tr><th>Feature</th><th>Predicate Device: Elecsys CK-MB STAT (two-step incubation) Assay (K132571)</th><th>CK-MB STAT (one-step incubation) Assay (modified)</th></tr>
<tr><th colspan="3">Labeled Performance Characteristics</th></tr>
<tr><td>Limitations, continued</td><td>• Testing was performed on 33 special drugs with concentrations shown in the table below. No interference with the assay was found. Criterion: Recovery within ± 10% compared to the unspiked reference sample.
<table>
<tr><th>Special Drug</th><th>Concentration</th></tr>
<tr><td>Carvedilol</td><td>50 mg/L</td></tr>
<tr><td>Propanolol</td><td>160 mg/L</td></tr>
<tr><td>Marcumar</td><td>9 mg/L</td></tr>
<tr><td>Reteplase</td><td>20 U/L</td></tr>
<tr><td>Suprarenin (Adrenalin)</td><td>3 mg/L</td></tr>
<tr><td>Methylprednislon</td><td>40 mg/L</td></tr>
<tr><td>Verapamil</td><td>480 mg/L</td></tr>
<tr><td>Lidocain</td><td>500 mg/L</td></tr>
<tr><td>Enalapril</td><td>40 mg/L</td></tr>
<tr><td>Captopril</td><td>150 mg/L</td></tr>
<tr><td>Lisinopril</td><td>40 mg/L</td></tr>
<tr><td>Aldactone (Spironolacton)</td><td>400 mg/L</td></tr>
<tr><td>Torasemid</td><td>5 mg/L</td></tr>
<tr><td>Insulin</td><td>150 I.U.</td></tr>
<tr><td>Tolbutamid</td><td>10.5 mg/L</td></tr>
<tr><td>Gentamycin</td><td>420 mg/L</td></tr>
<tr><td>Lovostatin</td><td>80 mg/L</td></tr>
<tr><td>Pravastatin</td><td>8 mg/L</td></tr>
<tr><td>Simvastin</td><td>80 mg/L</td></tr>
<tr><td>Bisprolol</td><td>20 mg/L</td></tr>
<tr><td>Nitrolingual (Glyceroltrinitrat)</td><td>1.6 mg/L</td></tr>
<tr><td>Heparin</td><td>7500 I.U.</td></tr>
<tr><td>Metropolol</td><td>200 mg/L</td></tr>
<tr><td>Molsidomin</td><td>16 mg/L</td></tr>
<tr><td>Nicardipin</td><td>160 mg/L</td></tr>
<tr><td>Nifedipin</td><td>60 mg/L</td></tr>
<tr><td>Propafenon</td><td>900 mg/L</td></tr>
<tr><td>Solatol</td><td>480 mg/L</td></tr>
<tr><td>Streptokkinase</td><td>10 000 000 I.U.</td></tr>
<tr><td>Urokinase</td><td>4200000 mg/L</td></tr>
<tr><td>Digoregen (Digoxin)</td><td>0.5 mg/L</td></tr>
<tr><td>Digimerck minor (Digitoxin)</td><td>0.21 mg/L</td></tr>
<tr><td>Clopidrogel</td><td>300 mg/L</td></tr>
</table></td><td>Same</td></tr>
</table>

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Special 510(k) Summary, *continued*

Assay Comparison		
Feature	**Predicate Device: Elecsys CK-MB STAT (two-step incubation) Assay (K132571)**	**CK-MB STAT (one-step incubation) Assay (modified)**
Labeled Performance Characteristics		
Limitations, *continued*	• In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings These limitations were established by testing performed with one human serum sample containing low levels of CK-MB and one human serum sample containing high levels of CK-MB.	Same

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Special 510(k) Summary, *continued*

Comparison of Assays—Similarities and Differences, continued

<table>
<tr><th colspan="3">Immunoassay Comparison</th></tr>
<tr><th>Feature</th><th>Predicate Device: Elecsys CK-MB STAT (two-step incubation) Assay (K132571)</th><th>CK-MB STAT (one-step incubation) Assay (modified)</th></tr>
<tr><th colspan="3">Labeled Performance Characteristics</th></tr>
<tr><td>Clinical Study/ reference range</td><td>
<table>
<tr><th></th><th>Gender</th><th>(N)</th><th>99th percentile (ng/mL)</th></tr>
<tr><td rowspan="2">All Subjects</td><td>Female</td><td>523</td><td>5.34</td></tr>
<tr><td>Male</td><td>568</td><td>10.36</td></tr>
<tr><td rowspan="2">Subjects with no Self-reported risk factors</td><td>Female</td><td>120</td><td>4.30</td></tr>
<tr><td>Male</td><td>102</td><td>7.70</td></tr>
</table>
Subjects represented "apparently heart healthy" population with exclusion of subjects with known poor cardiac health or known peripheral vascular disease only.
</td><td>Same</td></tr>
<tr><th colspan="3">Additional Performance Characteristics</th></tr>
<tr><td>Method Comparison
Elecsys CK-MB STAT on cobas e 411(two-step incubation) vs. Elecsys CK-MB STAT on cobas e 601 (one-step incubation)</td><td colspan="2">
<table>
<tr><td>n = 115
Min = 1.47 ng/ml
Max = 269 ng/ml</td><td>Passing/Bablok</td></tr>
<tr><td>Slope</td><td>0.976</td></tr>
<tr><td>Intercept</td><td>0.053</td></tr>
<tr><td>Tau</td><td>0.991</td></tr>
</table>
</td></tr>
</table>

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Special 510(k) Summary, *continued*

Standard/ Guidance Document Reference

In addition to FDA guidance regarding 510(k) submissions, the following standards were used for the performance studies.

- Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition. CLSI document EP5-A2, Volume 24, No. 25, August 2004.
- Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline. CLSI document EP 17-A, Volume 24, No. 34, October 2004.
- Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. CLSI document EP6-A, Volume 23, No. 16, April 2003.

Data for CK-MB STAT (one-step incubation) is on file at Roche Diagnostics.

Conclusion

The submitted information in this premarket notification supports a substantial equivalence decision. The differences between predicate and candidate do not impact the indications for use or technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 8, 2014

ROCHE DIAGNOSTICS
KELLI TURNER
REGULATORY AFFAIRS PRINCIPLE
9115 HAGUE ROAD
INDIANAPOLIS IN 46250

Re: K140404
Trade/Device Name: Elecsys CK-MB STAT Immunoassay
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: II
Product Code: JHY
Dated: April 07, 2014
Received: April 08, 2014

Dear Ms. Turner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

k140404

Device Name

Elecsys CK-MB STAT Immunoassay

Indications for Use *(Describe)*

Immunoassay for the in vitro quantitative determination of the MB isoenzyme of creatine kinase in human serum and plasma. Measurements of the MB isoenzyme of creatine kinase are used as an aid in the diagnosis of myocardial infarction.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ruth A. Chesler -S